Note: Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).
BACKGROUND OF THE INVENTION

[0001] The present invention relates to an ultrasonic imaging catheter inserted into a body cavity such as a vessel or a vas.

[0002] It has been known that the ultrasonic imaging catheter is inserted into a thin vessel such as a coronary artery of the heart or a vas such as a bile duct to form a tomogram of the vessel or the vas or to make a measurement of a blood flow therein. The ultrasonic imaging catheter comprises, for example, as shown in Figs. 16 and 17, a hollow outer sheath 2, an ultrasonic wave oscillator 3 disposed inside of a tip of the outer sheath 2, a drive shaft 6 of transferring driving force for rotating directly the oscillator 3 or an ultrasonic wave reflector 4, and signal cables 7 interconnecting the oscillator 3 and an outer electrical circuit 5. An outer driver 8 mechanically drives the drive shaft to scan an ultrasonic wave emitted from the oscillator.

[0003] It is desirable to make a tip portion of the catheter to be inserted into the blood vessel flexible to improve movement of the catheter within the blood vessel. It is further desirable that the tip portion of the catheter can be found easily under an X-ray fluoroscopy. Some catheters, therefore, have a mark for adding a contrast on a catheter body to point the position of the catheter. Some catheters have a metal of plate, ring or coil shape at the tip portion of the catheter that can point the X-ray contrast. An ultrasonic imaging catheter, as shown in Figs. 16 and 17, has a coil-shaped, elastic metallic member or a metallic piece 14 for adding the contrast at the tip portion thereof. The ultrasonic wave is transmitted and received through a portion 12 of an outer sheath 2 of the ultrasonic imaging catheter. The portion 12 is made of material having a good permeability for the ultrasonic wave such as olefin system resin and fluoride system resin. Thickness of the portion 12 is 100 µm or less because the thinner the portion 12, the better in permeability for the ultrasonic wave. Mechanical strength of the portion 12, therefore, is lower than a handle side shaft 15 of the catheter and is liable to kink. Furthermore, the ultrasonic imaging catheter has a stiff portion such as the ultrasonic wave oscillator. Therefore, a mechanical property of the catheter fails to change gradually among the stiff portion of the oscillator 3 or the like and the tip portion of the outer sheath 2 in which a coil-like elastic member is disposed. The ultrasonic imaging catheter hence fails to perform a preferable bend and is liable to kink so that the ultrasonic imaging catheter is poor in handling.

[0004] U.S.P. 5,095,911 discloses an ultrasonic imaging catheter that comprises an outer sheath, a housing secured to the outer sheath, an elastic member connected to a tip portion of the housing. The housing of the catheter is stiff and long such that a tip portion of the catheter including the housing is poor in flexibility and is hard to bend.

[0005] The catheter without any stiff housings as shown in Fig. 16 is preferable from a view point of the flexibility.

[0006] WO-93/16 642 discloses an ultrasonic imaging catheter according to the preamble of claim 1. A particular embodiment of an ultrasonic imaging guidewire comprises an outer sheath to be inserted into a body cavity, a drive shaft inserted into the outer sheath for transmitting mechanical driving force from a proximal portion to a tip portion thereof, wherein the drive shaft is rotatable by an outer driving source, and a housing secured to the drive shaft. In the housing, an acoustic imaging transducer is disposed. The housing is located inside of a tip portion of the outer sheath. In a floppy tip portion, an outer floppy layer of a helical coil cylinder is disposed. In its interior, a flexible core rod is disposed which is stationary with respect to the housing.

[0007] It is an object of the present invention to provide an ultrasonic imaging catheter of preferable handling because of improved flexibility and bend between a stiff portion of a tip side including the oscillator and an elastic member at a tip of the catheter.

[0008] A conventional ultrasonic imaging catheter comprises ultrasonic oscillators inside of a housing. Most of the housing of the conventional type is cylindrical to improve sliding between the housing and an outer sheath (See JP-A 5-212036 and JP-A 5-092003). A drive shaft 6 is formed with a metallic coil made of stainless steel (SUS304, SUS316, etc.) or the like. The housing and the drive shaft are connected to each other by brazing or welding so that the housing is made of the stainless steel (SUS304, SUS316, etc.) or the like similar to the drive shaft. One of electrodes of the oscillator secured to the housing must not be contacted with the housing to prevent a short among electrodes of the oscillator. To realize this, a method of packing the oscillator with a case of insulating material that is secured to the housing is carried out. According to the method, the oscillator is limited in an outer diameter to be small because of the thickness of the insulating material. A depth of transparency of the ultrasonic wave in an object to be measured and divergence of the ultrasonic wave in an azimuth direction are very important in the ultrasonic imaging catheter. In particular, it is desirable to use an oscillator largest in size to minimize the divergence in the azimuth direction and to deepen in the depth of the transparency of the ultrasonic wave when the ultrasonic catheter is thin in diameter, particularly 1 mm or less in outer diameter.

SUMMARY OF THE INVENTION

[0009] The present invention is defined in claims 1 and 15.
BRIEF DESCRIPTION OF THE DRAWINGS

[0010] The present invention is illustrated with reference to the accompanying drawings, in which:

Fig. 1 is a partially sectional view of an ultrasonic imaging catheter which is not part of the present invention, the catheter being attached to an outer unit. Fig. 2 is a partially sectional view of a handle portion (a connector) and the outer unit of an ultrasonic imaging catheter which is not part of the present invention.

Fig. 3A is a sectional view showing a structure of a transducer used in the ultrasonic imaging catheter of the present invention.

Fig. 3B is a sectional view showing a structure of another transducer used in the ultrasonic imaging catheter of the present invention.

Fig. 4 is a sectional view of a tip portion of an ultrasonic imaging catheter of an embodiment of the present invention.

Fig. 5 is a plane view showing a transducer of the ultrasonic imaging catheter shown in Fig. 4 and vicinities of the transducer.

Fig. 6 is a sectional view along an A-A line in Fig. 4.

Fig. 7 is a sectional view of an ultrasonic imaging catheter of another embodiment of the present invention.

Fig. 8 is a partial sectional view of an outer sheath used for the ultrasonic imaging catheter of the present invention.

Fig. 9 is a perspective view of an ultrasonic imaging catheter of another embodiment of the present invention.

Fig. 10 is an enlarged view showing a tip portion of the ultrasonic imaging catheter shown in Fig. 9 and vicinities of the tip portion.

Fig. 11 is an enlarged and sectional view of the tip portion of the catheter shown in Fig. 9.

Fig. 12 is an enlarged view showing an end portion of an assembly of drive shaft for the catheter shown in Fig. 9 and vicinities of the end portion.

Fig. 13 is a plan view showing a transducer of the assembly of the drive shaft shown in Fig. 12 and vicinities of the transducer.

Fig. 14 is a sectional view of the assembly of the drive shaft shown in Fig. 13.

Fig. 15 is an enlarged and sectional view of the tip portion of the catheter of another embodiment of the present invention.

Fig. 16 is a partially sectional view of a conventional ultrasonic imaging catheter attached to an outer unit.

Fig. 17 is a sectional view of a tip portion of the conventional ultrasonic imaging catheter.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0011] An ultrasonic imaging catheter of the present invention is described hereinbelow with regard to the attached drawings, the catheters of the Fig. 1 and 2 being catheters which do not fall under the present invention.

[0012] The ultrasonic imaging catheter 1 of this invention comprises an outer sheath 2 to be inserted into a body cavity, a drive shaft or driving shaft 6 inserted into the outer sheath 2, a housing 27 secured at a tip of the drive shaft 6, a handle portion (a connector) 20 connected with a proximal end of the outer sheath 2.

[0013] Fig. 1 shows an ultrasonic imaging catheter system 10 configured by attaching the ultrasonic imaging catheter 1 to an outer unit 13.

[0014] A housing 27 is disposed inside of a tip portion of the outer sheath 2 of the catheter. A transducer 11 is disposed in the housing 27. The transducer 11 has a function as an ultrasonic wave oscillator for transmitting and receiving an ultrasonic wave. The housing 27 is connected at a free end of the drive shaft 6 of coil shape.

[0015] The drive shaft 6 is formed with two layers of plates spiraled twice and the plates are made of stainless steel (SUS304, SUS316, etc.) or the like. The drive shaft preferably has breaking strength of 0.4 kgf or more. The drive shaft 6 may be formed with a wire or plate, which is made of metal or resin, spiraled once or multiply in a coil manner or in a blade manner. The drive shaft may be formed by winding a signal cable mentioned below around the wire having the breaking strength of 0.4 kgf or more.

[0016] The signal cable 7 formed by stranding two leads 7a and 7b is threaded into drive shaft 6. An end of the signal cable 7 positioned on the tip side of the catheter is connected with an oscillator formed in the transducer 11. Another end of the signal cable 7 positioned on the proximal side (on the handle side) of the catheter is connected with terminals 21 and 22 of the operational member 20. In more detail, as shown in Fig. 2, a tubular member formed by insulation material is inserted and fixed into the proximal end of the shaft 6. The terminal 22 is fixed to the proximal edge of the tubular member. The terminal 21 is fixed on the side surface of the middle portion of the tubular member. The end of the lead 7a is connected by the terminal 22. The end of the lead 7b is connected to the terminal 21 through an opening formed on the side of the tubular member.

[0017] The handle portion (the connector) 20 has, as shown in FIG. 2, a projection 25 to be engaged with an arresting member 13a of the outer unit 13. The projection 25 and the arresting member 13a are connected detachably.

[0018] The outer unit 13 comprises a transmitting-receiving circuit 5 and a driving source 8 including a motor 16. The outer unit 13 is electrically connected with a console C having a signal processing circuit and an image displaying unit.
The motor 16 as an outer driving source has a rotor (a rotating plate) 16a. A first cylindrical terminal 24 is secured at the center of the rotating plate 16a and a second cylindrical terminal 23 secured on the rotating plate 16a around the first cylindrical terminal 24 without any contact therebetween. The cylindrical terminals 23 and 24 rotate together with the rotating plate.

A rotational slip terminal member 26 that comprises a slip ring or the like connected with the transmitting-receiving circuit 5 is disposed inside of the outer unit 13. The terminal member 26 has a first terminal 26a and a second terminal 26b. The first terminal 26a is in contact with the second cylindrical terminal 23 on the rotational plate. The second terminal 26b is in contact with the first cylindrical terminal 24 on the rotational plate. The contacts between the respective terminals are kept while the rotational plate rotates.

The tubular member having the terminals 21 and 22 secured to the drive shaft 6 is engaged with an opening of the first cylindrical terminal 24 on the rotational plate. The proximal port (terminal 21) of the tubular member is allowed to enter into the second terminal 23 on the rotational plate and the proximal portion is engaged with a circular rib formed near the free end of an opening of the cylindrical terminal 23. The drive shaft 6, thereby, is connected with the rotational plate of the motor 16 detachably. Rotational force of the motor is transmitted to the drive shaft through the rotational plate and two cylindrical terminals 23 and 24.

The housing 27 is pipe-shaped and has an outer diameter approximately equal to that of the drive shaft 6. A fixing portion 18 of the transducer 11 is formed by cutting the pipe-shaped member in an axial direction around the center by a predetermined length and in a radial direction by almost a half of a circle of the pipe-shaped member. The housing 27 is made of metal, resin or ceramics or the like. The housing 27 is made of metallic material such as stainless steel (SUS304, SUS316, etc.) or ceramic material such as alumina and zirconia with a view to providing connection strength and reinforcing the transducer 11.

A first, coil-shaped elastic member 41 spiraled once is formed at the free end of the catheter 2 (at the tip of the outer sheath). The first elastic member 41 protrudes to the tip of the outer sheath 2. A second elastic member 19 is connected with the free end of the housing 27. The second elastic member 19 extends toward a tip direction of the catheter. The second elastic member extends up to inside of the first elastic member to reinforce the first elastic member 41. That is, a tip of the second elastic member 19 is positioned within the first elastic member 41.

The second elastic member 19 is a rod-like member and is made of metal having an elastic property such as stainless steel (SUS304, SUS316, etc.), super elastic metal such as Ni-Ti system alloy, resin such as polyacetal or the like. The elastic member 19 is preferably made of the super elastic metal such as Ni-Ti system alloy with a view to promoting connection strength with the housing 27 and its own elasticity. The second elastic member 19 is connected at the tip portion of the housing 27 by adhering, brazing, welding or the like. It is preferable to insert the elastic member 19 by a length of about 0.5 to 20 mm into the coil-like elastic member 41 that is connected to an inner surface of the outer sheath 2 of the catheter.

A rotational slip terminal member 26 that comprises a slip ring or the like connected with the transmitting-receiving circuit 5 is disposed inside of the outer unit 13. The terminal member 26 has a first terminal 26a and a second terminal 26b. The first terminal 26a is in contact with the second cylindrical terminal 23 on the rotational plate. The second terminal 26b is in contact with the first cylindrical terminal 24 on the rotational plate. The contacts between the respective terminals are kept while the rotational plate rotates.

The tubular member having the terminals 21 and 22 secured to the drive shaft 6 is engaged with an opening of the first cylindrical terminal 24 on the rotational plate. The proximal port (terminal 21) of the tubular member is allowed to enter into the second terminal 23 on the rotational plate and the proximal portion is engaged with a circular rib formed near the free end of an opening of the cylindrical terminal 23. The drive shaft 6, thereby, is connected with the rotational plate of the motor 16 detachably. Rotational force of the motor is transmitted to the drive shaft through the rotational plate and two cylindrical terminals 23 and 24.

The housing 27 is pipe-shaped and has an outer diameter approximately equal to that of the drive shaft 6. A fixing portion 18 of the transducer 11 is formed by cutting the pipe-shaped member in an axial direction around the center by a predetermined length and in a radial direction by almost a half of a circle of the pipe-shaped member. The housing 27 is made of metal, resin or ceramics or the like. The housing 27 is made of metallic material such as stainless steel (SUS304, SUS316, etc.) or ceramic material such as alumina and zirconia with a view to providing connection strength and reinforcing the transducer 11.

A first, coil-shaped elastic member 41 spiraled once is formed at the free end of the catheter 2 (at the tip of the outer sheath). The first elastic member 41 protrudes to the tip of the outer sheath 2. A second elastic member 19 is connected with the free end of the housing 27. The second elastic member 19 extends toward a tip direction of the catheter. The second elastic member extends up to inside of the first elastic member to reinforce the first elastic member 41. That is, a tip of the second elastic member 19 is positioned within the first elastic member 41.

The second elastic member 19 is a rod-like member and is made of metal having an elastic property such as stainless steel (SUS304, SUS316, etc.), super elastic metal such as Ni-Ti system alloy, resin such as polyacetal or the like. The elastic member 19 is preferably made of the super elastic metal such as Ni-Ti system alloy with a view to promoting connection strength with the housing 27 and its own elasticity. The second elastic member 19 is connected at the tip portion of the housing 27 by adhering, brazing, welding or the like. It is preferable to insert the elastic member 19 by a length of about 0.5 to 20 mm into the coil-like elastic member 41 that is connected to an inner surface of the outer sheath 2 of the catheter.

The first elastic member 41 is secured to the outer sheath 2 by inserting a proximal end of the member 41 into the open end of the sheath 2. A distal end of the first elastic member 41 protrudes to the open end of the sheath 2. It is preferable to shorten a length of the connecting portion between the coil-shaped elastic member 41 and the open end of the outer sheath 2 while keeping enough connection strength therebetween. It is preferable to be about 0.5 to 10 mm long. The coil-shaped elastic member 41 is conical in shape and its diameter tapers in the tip direction.

The coil-shaped elastic member 41 at the tip of the catheter is made of a material similar to that of the elastic member 19. Metal such as Pt, Ir, Au or alloy thereof (high X-ray contrast material) is preferable for the material of the elastic member 41 so as to enhance the contrast in an image formed by an X-ray.

In the ultrasonic imaging catheter 1 of the present invention, the tip of the rod-like elastic member 19 is always positioned within the coil-shaped elastic member 41 even when the catheter bends. A portion between the housing 27 and the coil-shaped elastic member 41 at the tip of the catheter is improved in bending and kinking in comparison with the conventional catheter that comprises only an outer sheath and no elastic members.

In particular, the second elastic member 19 located from the tip of the housing 27 to inside of the first elastic member 41 is disposed in the device of the present embodiment. A section from the end of the housing 27 to the tip of the catheter is improved in bending because no portion in which physical property varies radically is formed.

The outer sheath 2 of the catheter comprises an ultrasonic wave transmitting-receiving portion 12 of the tip side and a main body 15 of the handle side. The portion 12 and the body 15 are allowed to be formed with different material. The outer sheath 2 or the main body 15 of the sheath is formed with so-called catheter material. That is, a tube made of polyolefin resin, polyurethane resin, polyacetal resin, polyimide resin, fluoride resin, or the like, a tube made of stainless steel (SUS304, SUS316, etc.) or the like, a tube made of super elastic metal such as Ni-Ti system alloy, and a combined tube configured by winding a resin wire or a stainless steel (SUS304, SUS316, etc.) wire or the like in a coil manner or in a blade manner. Thickness of the sheath 2 and 15 is 30 to 300 μm and it is desirable that the sheath has at least 0.4 kgf of tensile break strength. It is desirable to form the ultrasonic wave transmitting-
receiving portion 12 at the tip side of the catheter with a material of good permeability in the ultrasonic wave, i.e. polyolefin system resin, polyurethane system resin or fluoride system resin. Thickness of the resin to form the transmitting-receiving portion 12 is about 10 to 100 μm, preferably.

[0030] It is allowed to coat an outer surface and an inner surface of the outer sheath 2 (in particular the outer surface) with hydrophilic resin, fluoride resin or silicone resin or the like in 1 to several tens μm thickness. Sliding resistance of the outer and inner surfaces of the outer sheath 2 decreases by the treatment mentioned above. It is allowed to coat or fix the outer surface of the outer sheath with antithrombus material. Coating with the antithrombus material is realized by coating the outer surface of the shaft with a resin including the antithrombus such as heparin.

[0031] Fig. 3A is a sectional view showing a configuration of a transducer 11 utilized for the ultrasonic imaging catheter 1 of the present invention. The transducer 11 includes an ultrasonic wave oscillator 3. The oscillator performs transmitting and receiving of ultrasonic waves. The oscillator 3 is formed by evaporating or printing electrodes 32 on both surfaces of a piezoelectric layer 31 of a rectangular PZT. The piezoelectric layer 31 may be circular in shape. A back layer 33 is disposed backside of the oscillator 3 to absorb or to attenuate the ultrasonic wave. The back layer 33 is made of epoxy resin or the like in which metallic powder or inorganic powder is mixed. The back layer 33 in Fig. 3A forms projections and recesses to offset a reflected wave from a back side of the back layer 33 by interference. A difference D in thickness between the projections and recesses is λ/4 where λ is a wave length of the ultrasonic wave at a transmitting frequency in the back layer 33. The back layer 33 may be formed, as shown in Fig. 3B, by alternating a low acoustic impedance layer 36 (Z = 8 x 10¹⁰ Kgm²s or less) and a high acoustic impedance layer 37 (Z = 20 x 10⁶ Kgm²s or more) to attenuate influence of the reflected wave from the back side of the back layer 33.

[0032] An acoustic alignment layer 35 so called is disposed on an acoustic emission surface of the oscillator 3. The acoustic alignment layer 35 is so constructed that its thickness (D) equals λ/4 where λ is a wave length of the ultrasonic wave at the transmitting frequency in the alignment layer. Only one acoustic alignment layer is shown in the figures, but two or more layers may be provided.

[0033] Next, an explanation of an ultrasonic imaging catheter 30 of another embodiment of the present invention will be made by referring to Figs. 4, 5 and 6. It is noted that basic configuration of the ultrasonic imaging catheter 30 is similar to the ultrasonic imaging catheter 1 shown in Figs. 1 and 2 mentioned above.

[0034] In the ultrasonic imaging catheter 30 of the embodiment, a transducer 11 is secured to a housing 27 with an adhesive or the like in a manner that deviation in a perpendicular direction of an ultrasonic wave transmitting-receiving surface of the transducer with respect to an axial direction of the ultrasonic imaging catheter 11 should be kept about ± 10°. The housing 27 is connected with a tip of a drive shaft 6 with at least 0.4 kgf of connection strength by adhering, brazing or welding.

[0035] In the ultrasonic imaging catheter 30 of the embodiment, a coil-shaped of elastic member 19 is connected with a free end of the housing 27. The elastic member 19 tapers its diameter towards the tip of the catheter. The coil-shaped elastic member 19 is formed with monolayer or multilayer elastic strip and spiraled once or multiply. It is preferable to spiral the outer most layer in the direction by which the strip is loosened as the drive shaft rotates in a case where the strip comprises the multilayer elastic strip. It is preferable to spiral a strip in the direction by which the strip is loosened as the drive shaft rotates in a case where the strip comprises the monolayer elastic strip. Fig. 4 shows a monolayer coil and a clockwise rotation of the drive shaft. The elastic member 19 extends to be inserted into a coil-shaped elastic member 41, which is connected at a free end of the outer sheath, by a length of about 0.5 to 20 mm.

[0036] Material to form the coil-shaped elastic members 19 and 41 is similar to that mentioned above.

[0037] Signal lines 7a and 7b are connected with electrodes on each surface of the oscillator 3, respectively. The signal cables may be combined into a coaxial line as well as a stranded line in Fig. 4.

[0038] The outer sheath 2 of the catheter 30 comprises a handle side (a shaft body) 15 and a tip side (a tip portion) 12. An outer surface of a tip portion of the handle side 15 is treated to taper its thickness towards the tip. An inner surface of a proximal portion of the tip side 12 is treated to taper its thickness towards the proximal end. The tip portion of the main body 15 thus configured is inserted into a proximal end of the tip portion 12 and secured to each other to form a connecting portion. The connecting portion thus formed has an almost even outer diameter therethrough. The connecting portion thus formed realizes a relatively long connecting portion, high strength in the connecting portion. And, furthermore, the connecting portion has no point in which a mechanical property varies radically, that is the mechanical property varies gradually through the connecting portion. The outer sheath 2 is thereby improved through the connecting portion in bending, flexibility and so on.

[0039] A resin cover 17 is disposed at the tip of the ultrasonic imaging catheter 30 to cover a difference in level between the tip portion 12 of the sheath and a portion of the elastic member 41 projected from the tip portion 12. A free end of the resin cover 17 is formed conical as is the free end of the elastic member 41. The resin cover 17 assists the free end of the elastic member in keeping its shape. The resin cover 17 is made of flexible synthetic resin such as silicone rubber, polyurethane, olefin system elastomer, polyamide elastomer.
As shown in Figs. 5 and 6, the pipe-shaped housing 27 has a fixing portion 18 of the transducer 11 that is formed by cutting the pipe-like member in an axial direction around the center by a predetermined length and in a radial direction by almost a half of a circle of the pipe-like member. The transducer 11 is set into the fixing portion 18 as directing an acoustic alignment layer 35 to an open side of the fixing portion and a back layer 33 to a bottom side of the fixing portion. The transducer 11 is secured to the housing 27 with an adhesive.

Next, an explanation of an ultrasonic imaging catheter 40 of another embodiment shown in Fig. 7 will be made.

In the ultrasonic imaging catheter 40 of the embodiment, a coil-shaped elastic member 19 is connect- ed to a free end of a housing 27. The member 19 is made of metal such as stainless steel (SUS304, SUS316, etc.), Ni-Ti system alloy A coil-shaped member 41 having a X-ray contrast is attached inside of a tip portion 12 of an outer sheath by an adhesive 42. A free end of the elastic member 19 is so formed that it is positioned within the coil-shaped member 41. A free end of the coil-shaped member 41 tapers its diameter towards the tip of the catheter. A supporting member 43 is disposed in the free end of the coil-shaped member 41. The supporting member comprises a wire portion or at least a plate portion. It is preferable to form the supporting member 43 with metal or at least plate steel such as stainless steel (SUS304, SUS316, etc.), Ni-Ti system alloy. The supporting member 43 improves mechanical strength or flexibility of the coil-shaped member 41. The supporting member 43 comprises a hemisphere-like tip portion 43a, a connecting portion 43b extending in a rear direction from the hemisphere-like tip portion 43 with an increase in its diameter, and a disk portion 43c formed at the rear end of the connecting portion 43b. A circumferential surface of the disk portion 43c is engaged with an inner surface of the coil-shaped member 41. A tip of the coil-shaped member 41 is in contact with a rear surface of the hemisphere-like tip portion 43a.

The configuration of the outer sheath is not limited to the above mentioned and a configuration of the catheter 45 shown in Fig. 8 is also available. Fig. 8 is a sectional view showing a part of modified outer sheath used for the ultrasonic imaging catheter 45 of the present invention. In the outer sheath, a handle side (a main body) 15 comprises two layers of an inner layer 48 and an outer layer 49. A tip side 12 including an ultrasonic wave transmitting-receiving unit is formed with only the outer layer 49. The inner layer 48 of the handle side (the main body) 15 is formed with metallic tube of stainless steel (SUS304, SUS316, etc.), super elastic metallic tube of Ni-Ti system alloy or tube configured by spiraling stainless steel (SUS304, SUS316, etc.) strip in a coil manner or in a blade manner. The outer layer 49 is formed with resin such as polyolefin system resin, fluoride system resin or polyamide. The outer layer 49 is formed as follows. That is, inserting an inner tube into a heat shrinkable tube as the outer layer and heating them to shrink the outer heat shrinkable tube to coat the inner tube. Inserting an inner tube into a resin tube, which is swelled by a solvent, as the outer layer and drying the solvent to shrink the outer resin tube to coat the inner tube. Dipping the inner tube with resin to be the outer layer to coat the inner tube. Extruding melted resin to be the outer layer on an outer surface of the inner tube to coat the inner tube.

Explanation for an ultrasonic imaging catheter 100 of another embodiment of the present invention will be made by referring to Figs 9, 10, 112, 13 and 14.

The ultrasonic imaging catheter 100 of the present embodiment comprises, as shown in Figs. 9 and 11, an outer sheath assembly 102 to be inserted into the body cavity, a drive shaft assembly 106 inserted into the outer sheath assembly 102, and a connector 120 secured to a proximal end of the outer sheath assembly 102.

The outer sheath assembly 102 comprises a tip portion 112 and main body 115. The tip portion 112 of the outer sheath assembly 102 comprises a tip-center portion 112b having a coil-shaped elastic member 141, a tip end portion 112a and a tip base portion 112c (an ultrasonic wave transmitting and receiving portion) having no elastic member 141 in front of and in the rear of the center portion 112b. A transducer 111 is disposed inside of the tip base portion 112c.

A tip member 117 is connected to the tip of the outer sheath assembly 102. A through hole 117a provided to the tip member 117 communicates between the interior and exterior of the outer sheath assembly 102. The tip member 117 shaped as a hemisphere on the tip side thereof is secured at the free end of the outer sheath assembly 102. A coil-shaped elastic member (a first elastic member) 141 is provided to the outer sheath assembly 102. The elastic member 141 extends predetermined length towards the proximal end side from a position slightly shifted to the proximal end side from the free end of the outer sheath assembly 102. The coil-shaped elastic member 141 is fixed by being sandwiched between an outer layer 102a and an inner layer 102c forming the outer sheath assembly 102. The coil-like elastic member 141, therefore, is not exposed so that the catheter 100 is improved in movement in a guiding catheter. It becomes that the top of a catheter is flexible, because the coiled flexibility member 141 is not present in the top part. This reduces the effect whereby an inner wall of a blood vessel receives damage by the top of a catheter, when the top of a catheter made contact with the inner wall of a blood vessel by this.

There are also benefits in using a device wherein a tip member 137 does not have the through hole, like catheter 150 shown in Fig. 15. In this case, a closed inner space of a catheter may be filled with a liquid 138 harmless to a living body, such as isotonic sodium chloride solution. It becomes by this that priming work at the time of use of the catheter is not needed.
Length of the coil-shaped elastic member 141 is preferably 5 to 50 mm, and 10 to 30 mm more in preference, but it depends on length of the whole catheter. Length of a distal portion 112a without the elastic member 141 may be 1 to 10 mm, 1 to 5 mm in preference. The elastic member 141 can extend up to the free end of the outer sheath assembly 102. The coil-shaped elastic member 141 is preferably made of metal, in particular, material (metal) for producing a high contrast in an image formed with an X-ray such as metal of Pt, Ir, Au, etc., alloy thereof or the like.

The outer sheath assembly 102 is a tube-like member of multi layers as shown in Fig. 11. The assembly 102 has at least an outer layer 102a and an inner layer 102c that extend from the proximal end of the outer sheath assembly to the tip end thereof. The main body 115 of the outer sheath assembly 102 includes the outer layer 102a, the inner layer 102c and an intermediate layer 102b between the outer layer 102a and the inner layer 102c. The tip base portion 112c and the tip end portion 112a comprise only the outer layer 102a and the inner layer 102c. The intermediate layer 102b is a reinforcement layer and made of stiff materials.

Resin being good in permeability of the ultrasonic wave is preferable for the material of the outer layer 102a and the inner layer 102c of the outer sheath assembly 102. That is, polyolefin system resin, polyurethane system resin, fluoride system resin or the like may be used. Polyethylene, factually low density polyethylene for the outer layer and high density polyethylene for the inner layer, is more preferable. Thickness of the portion 112c for the ultrasonic wave transmitting and receiving in the outer sheath assembly is about 10 to 100 µm in preferable. A tube made of rigid resin, elastic metal, super elastic metal or the like is available for the reinforcement layer 102b.

The following material is available for the elastic metal. That is substantial metal such as steel, tungsten, copper, etc., or alloy thereof (such as austenitic system stainless steel, for example, SUS304, SUS316 and SUS321, maraging stainless steel, Cu-Zn alloy and Cu-Sn alloy). The austenitic system stainless steel is more preferable.

Super elastic metal means alloy generally called a shape-memory alloy which shows a superelasticity at the body temperature (around 37°C). Super elasticity here means the capability of super elastic metal to recover almost its former shape at the temperature at which it is used after it is deformed (bent, elongated or compressed) to such a degree that ordinary metal undergoes permanent deformation. Preferable superelastic alloys include Ti-Ni binary alloy consisting essentially of 49 to 58 atom percents of Ni (the balance of Ti), Cu-Zn binary alloy consisting essentially of 38.5 to 41.5 wt% of Zn (the balance of Cu), Cu-Zn-X ternary alloy obtained by replacing part of Cu-Zn alloy with 1 to 10 wt% of X (X = Be, Si, Sn, Al or Ga), and Ni-Al binary alloy consisting essentially of 36 to 38 atom percents of Al (the balance of Ni). Of these alloys, Ti-Ni binary alloy is especially preferable. The mechanical property of Ti-Ni alloy can be changed as desired by replacing part of Ti-Ni alloy with 0.01 to 2.0 atom percents of X (X = Co, Fe, Mn, Cr, V, Al, Nb, Pd, B, etc.).

The intermediate layer 102b includes spiral slit extending from a tip end toward the other end. A tip portion of the intermediate layer has the slit and the remainder portion of the intermediate layer has not any slits. The tip portion of the intermediate layer is a deformable portion which is more flexible than the remainder. The tip portion of the elastic metal tube is flexible in that its side wall is deformable radially inward. The spiral slit is preferably formed such that each width of the slit tapers or decreases gradually from the tip end toward the other end, that is the width widens or increases gradually toward the tip side. Each of the slits has the maximum width at the tip end of the elastic metal tube. The deformability of the elastic metal tube, therefore, increases toward the tip thereof. Preferably one to three slits are formed with approximately even pitch. Also preferably, the slit has a maximum width of about 0.05 to 0.5 mm at the tip end (as measured in a circumferential direction). The width of the slit is preferably about 1/6 to 3/2, more preferably about 1/3 to 1/1 of the outer diameter of the elastic metal tube.

The pitch between the spiral slits may be varied such that the pitch is shorter at the tip end and is longer at the proximal end. Where the pitch of the slits varies, the pitch is preferably about 0.3 to 3.0 mm at the tip end and about 5 to 10 mm at the proximal end. In an intermediate region of the elastic metal tube between the tip end and the other end, the pitch of the slits is an intermediate value of the both ends or changes gradually in preferable. Preferably the slits have the varying pitch and the varying width as described above.

The slit is formed in the metal tube by any of conventional techniques including laser machining (e. g., YAG laser), electric discharge machining, chemical etching, machining, and combinations thereof.

It is allowed to coat an outer surface and an inner surface of the outer sheath assembly with hydrophilic resin, fluoride resin or silicone resin or the like in 1 to several tens µm thickness. Sliding resistance of the outer and inner surfaces of the outer sheath assembly decreases by the treatment mentioned above. In addition, it is allowed to coat or fix the outer surface of the outer sheath assembly with antithrombus material Coating with the antithrombus material is realized by coating the outer surface of the assembly or the resin including the antithrombus such as heparin. It is preferable that the outer surface of the outer sheath assembly 102 has high lubricity or wettability, which reduces the sliding friction and makes easier the insertion into a hollow organ or the body cavity of the living body. The high lubricity or wettability is realized by introducing an appropriate kind of functional group into a resin coat of the outer layer 102a and, thereafter, coating or fixing the resin.
stainless steel are preferable. The number of layers of specially semiaustenitic) stainless steel and maraging mentioned superelastic alloy and stainless steel such as acoste. For the material of the drive shaft body, the afore-

- **Fig. 12** shows a shaft body 106a, a housing 127 for a transducer secured to a tip end of the shaft body 106a, and a rod-like elastic member 119 secured to a free end of the housing 127.

- **[0058]** The drive shaft assembly 106 comprises, as shown in Fig. 12, a shaft body 106a, a housing 127 for a transducer secured to a tip end of the shaft body 106a, and a rod-like elastic member 119 secured to a free end of the housing 127.

- **[0059]** The elastic member 119 is a rod-like member made of elastic metal such as stainless steel, super elastic metal, resin such as polyacetal or the like. The super elastic metal or the elastic metal is, in particular, preferable. The superelastic metal may be constituted as explained above. The rod-like member of the present embodiment is shaped like a coil due to its high flexibility.

- **[0060]** The second elastic member 119 of the drive shaft assembly 106 is approximately 2 to 30 mm long, preferably. It is more preferably 3 to 20 mm long. A free end of the second elastic member 119 is, as shown in Fig. 11, inserted into a proximal end portion of the first elastic member 141. That is, the free end of the second elastic member 119 is located inside of the first elastic member 141. The elastic member 141 and the elastic member 119 reinforce with each other. Therefore, change in physical property around the proximal end portion of the coil-shaped elastic member 141 is smoothed. It is thereby prevented that the catheter kinks around the proximal end portion of the coil-shaped elastic member 141. In a similar manner, change in physical property of the catheter around the free end of the elastic member 119 is smoothed by the coil-shaped elastic member 141. It is thereby prevented that the catheter kinks around the free end of the elastic member 119. The elastic member is preferably inserted into the portion in which the coil-shaped elastic member 141 is formed by approximately 0.5 to 20 mm. The elastic member 119 is connected with the free end of the housing 127 by adhering, brazing, welding or the like.

- **[0061]** The drive shaft body 106a is formed with two layers of plates spiraled twice and the plates are made of stainless steel (SUS304, SUS316, etc.) or the like. The drive shaft body preferably has breaking strength of 0.4 kgf or more. The drive shaft body 106a may be formed with a wire or plate, which is made of metal or resin, spiraled once or multiply in a coil manner or in a blade manner. The drive shaft body may be formed by winding a signal cable mentioned below around the wire having the breaking strength of 0.4 kgf or more.

- **[0062]** Factualy, the drive shaft body 106a comprises a coil. For the material of the drive shaft body, the aforementioned superelastic alloy and stainless steel such as precipitation hardening (PH stainless steel, especially semiaustenitic) stainless steel and maraging stainless steel are preferable. The number of layers of winding of the coil is not limited to one. A multi-layer structure consisting of two or more layers is preferable in order to increase torque transmissibility. In such a multilayer structure, it is preferable to reverse the direction of winding alternately layer by layer. By this structure, the drive shaft body is improved in transmissibility of pressure given on the proximal end of the catheter and is also improved in torque transmissibility.

- **[0063]** As shown in Figs. 13 and 14, the housing 127 for receiving the transducer 11 is a cylindrical member having a diameter approximately equal to that of the drive shaft body 106a. The housing 127 has a fixing portion 118 for the transducer 11 and the fixing portion 118 is formed by cutting a side surface of the cylindrical member in an axial direction around the center by a predetermined length and in a radial direction by almost half of a circle of the cylindrical member. A tip-side wall of the fixing portion of the present embodiment inclines. For the material of the housing 127, metal, resin, ceramics or the like is available. A tip end portion of the drive shaft body 106a is formed smaller in diameter than the remainder. The tip end portion is inserted into a proximal end of the housing 127. It is preferable to interpose insulating material between the tip end portion of the drive shaft body and the housing 127 in a case where the housing 127 is made of conducting material.

- **[0064]** The transducer 11 is so housed in the fixing portion that an outer surface of an ultrasonic wave transmitting-receiving surface exposes. For the transducer 11, the one shown in Fig. 3B is available. The transducer 11 is housed in the housing 127 and fixed thereto with adhesive as being its acoustic alignment layer 35 outside and its back layer 33 inside of the housing 127 as shown in Fig. 14. Stranded signal cables 107a and 107b, which are connected with the electrodes 32a and 32b of the transducer 11 respectively, are threaded into the drive shaft body 106a. Each of the signal cables is connected with terminals (not shown) of a connector 120 at their proximal end (handle side). The handle portion (the connector 120) is configured similar to that shown in Fig. 2.

- **[0065]** Explanation of ultrasonic wave scanning by the ultrasonic imaging catheter of the present invention will be made hereinbelow. The explanation of the ultrasonic wave scanning will be made by referring to Fig. 1, but it covers all of the embodiments mentioned above.

- **[0066]** The motor 16 inside of the outer unit 13 rotates to make a rotational movement and the rotational movement is transferred to the drive shaft 6 through the terminals 21 and 22 in the connector 20 of the catheter. The housing 27 secured to the tip end of the drive shaft 6 is thus rotated while performing transmitting and receiving of the ultrasonic wave by the transducer. The ultrasonic wave transmitted and received by the transducer 11 is scanned in a radial direction of the catheter 2 to reconstruct an ultrasonic wave image. The ultrasonic wave image thus obtained is a sectional image or a tomogram in the radial direction of the vessel and the...
vas. A tomogram in an axial direction of the vessel and vas may be reconstructed by moving the ultrasonic imaging catheter in the axial direction thereof. The tomogram in the axial direction is also obtained by constructing the catheter and the outer unit to move the drive shaft 6 in the axial direction of the catheter.

[0067] Explanation of a method of handling the ultrasonic imaging catheter of the present invention in the blood vessel will be made hereinbelow.

[0068] The handling of the ultrasonic imaging catheter is similar to that of a conventional blood catheter, that is, inserting an introducer or the like into a blood vessel from outside of a living body. A guiding catheter, through which a guide wire is threaded, is inserted into the introducer. The ultrasonic imaging catheter of the present invention is inserted into the guiding catheter after the tip of the guide wire arrives at an object portion to be diagnosed or treated. Thereafter, the tomogram of the vessel is reconstructed according to the ultrasonic wave handling method mentioned above. The guide wire may remain inside the guiding catheter or be pulled out from the guiding catheter while reconstructing the tomogram. The handling of the ultrasonic imaging catheter of the present invention is not limited to the case where the guiding catheter is used. The ultrasonic imaging catheter of the present invention may be inserted into a guide wire rumen of a treating catheter such as a balloon catheter. In such a case, an outer diameter of the ultrasonic imaging catheter is 0.25 to 0.97 mm in preference and 0.35 to 0.46 is more in preference.

[0069] In the ultrasonic imaging catheter of the present invention, the free end of the second elastic member is inserted into the coil-shaped first elastic member. The portion between the housing and the coil at the tip portion of the catheter is reinforced to improve flexibility and kinking. Therefore, the catheter is improved in movement in the vessel or the vas of the body cavity and handling of the ultrasonic imaging catheter becomes good.

[0070] In the ultrasonic imaging catheter of the present invention, the housing for housing the ultrasonic wave oscillator is made of insulating ceramic material. The insulation resistance of the housing is thus made high so that a short between the electrodes of the oscillator does not occur even when the oscillator is in direct contact with the housing. An oscillator largest in size but it is allowed to be set in the housing is available. Therefore, in a case where the present invention is applied to a thin ultrasonic imaging catheter of 1 mm or less in diameter, an ultrasonic wave oscillator of large enough for such a size of the catheter is available. It is thereby realized to be deeper in density of wave of the object and smaller in divergence of the azimuth direction.

Claims

1. An ultrasonic imaging catheter (1, 30, 40, 50, 100) comprising:
   - an outer sheath (2, 102) insertable into a body cavity, said outer sheath having a tip side and a tip portion;
   - a drive shaft (6, 106) positioned in the outer sheath for transmitting mechanical driving force from a proximal side to a tip side of the drive shaft, the drive shaft being rotatable by an outer driving source (8, 16);
   - a housing secured (27, 127) to the drive shaft in which an ultrasonic wave oscillator (3, 11, 111) or both the ultrasonic wave oscillator and an ultrasonic wave reflector are disposed, the housing having a tip portion and the housing being located inside a tip portion of the outer sheath;
   - a first elastic member (41, 141) disposed at the tip portion of the outer sheath and at a tip portion of the catheter;
   - a second elastic member (19, 119) disposed at the tip portion of the housing, the second elastic member extending toward the tip portion of the catheter and being located inside of the first elastic member;

   characterized in that the second elastic member is a coil.

2. An ultrasonic imaging catheter according to claim 1, wherein length of a portion of the second elastic member that is inserted into the first elastic member is 0.5 to 20 mm.

3. An ultrasonic imaging catheter according to any of the preceding claims, wherein the outer sheath has a reinforcement layer having a spiral slit provided to a tip portion thereof.

4. An ultrasonic imaging catheter according to any of the preceding claims, wherein at least a part of the second elastic member is made of supereleastic metal.

5. An ultrasonic imaging catheter according to any of the preceding claims, wherein the first elastic member comprises a through hole communicating between the interior and exterior of the catheter.

6. An ultrasonic imaging catheter according to any of the preceding claims, wherein the first elastic member is made of material having a high X-ray contrast.

7. An ultrasonic imaging catheter according to any of the preceding claims, wherein a diameter of the
second elastic member tapers toward the tip portion of the catheter.

8. An ultrasonic imaging catheter according to any of the preceding claims, wherein a diameter of the first elastic member tapers toward the tip portion of the catheter.

9. An ultrasonic imaging catheter according to claim 1, wherein the first elastic member has a supporting member inserted in a tip portion of the first elastic member.

10. An ultrasonic imaging catheter according to any of the preceding claims, wherein the ultrasonic wave oscillator comprises an ultrasonic wave oscillating section included in an ultrasonic wave transducer.

11. An ultrasonic imaging catheter (50) according to any of the preceding claims, wherein the housing is formed of an insulating material

12. An ultrasonic imaging catheter according to claim 11, wherein the housing is formed of ceramics.

13. An ultrasonic imaging catheter according to claim 12, wherein the ceramics is alumina or zirconia.

14. An ultrasonic imaging catheter according to any of claims 11 to 13, wherein the housing is made cylindrical and has a cut portion for receiving the ultrasonic wave oscillator at a center in an axial direction of the cylindrical housing, and the oscillator being so received in the cut portion to contact with the housing.

15. An ultrasonic imaging catheter (100) comprising:
- an outer sheath assembly (102) having an outer layer (102a) and an inner layer (102c) and a tip side and a tip portion;
- a drive shaft (106) positioned in the outer sheath assembly;
- a housing (127) secured to the drive shaft in which an ultrasonic wave oscillator (11) is disposed, the housing having a tip portion and the housing being located inside of a tip portion of the outer sheath assembly;
- a first elastic member (141) disposed at the tip portion of the outer sheath assembly and at a tip portion of the catheter and between the outer layer and the inner layer;
- a second elastic member (119) disposed at the tip portion of the housing, the second elastic member extending toward the tip portion of the catheter and being located inside of the first elastic member;

characterized in that the second elastic member is a coil.

16. An ultrasonic imaging catheter according to claim 15, wherein the outer sheath assembly has a tip member connected to the tip of the outer sheath assembly and having a opening.

17. An ultrasonic imaging catheter according to claim 15, wherein the outer sheath assembly has a closed tip member connected to the tip of the outer sheath assembly and the catheter has a closed inner space filled by a liquid.

18. An ultrasonic imaging catheter according to any of claims 15 to 17, wherein a body portion of the outer sheath assembly has a reinforcement layer between the outer layer and the inner layer.

19. An ultrasonic imaging catheter according to claim 18, wherein the reinforcement layer has a spiral slit provided to a tip portion thereof.

20. An ultrasonic imaging catheter according to any of claims 15 to 19, wherein the ultrasonic wave oscillator comprises an ultrasonic wave oscillating section included in an ultrasonic wave transducer.

Patentansprüche

1. Ultraschall-Bildgebungskatheter (1, 30, 40, 50, 100), umfassend:
- eine äußere Umhüllung (2, 102), die in einen Körperhohlraum einfügbar ist, wobei die äußere Umhüllung eine Endseite und einen Endabschnitt aufweist;
- eine Antriebswelle (6, 106), die zum Übertragen einer mechanischen Antriebskraft von einer proximalen Seite auf eine Endseite der Antriebswelle in der äußeren Umhüllung angeordnet ist, wobei die Antriebswelle durch eine äußere Antriebsquelle (8, 16) drehbar ist;
- ein Gehäuse (27, 127), das an der Antriebswelle befestigt ist und in dem ein Ultraschallwellenreflektor (3b, 111) oder sowohl der Ultraschallwellenreflektor als auch ein Ultraschallwellenreflektor angeordnet ist, wobei das Gehäuse einen Endabschnitt aufweist und das Gehäuse sich innerhalb eines Endabschnitts der äußeren Umhüllung befindet;
- ein erstes elastisches Glied (41, 141), das am Endabschnitt der äußeren Umhüllung und an einem Endabschnitt des Katheters angeordnet ist;
- ein zweites elastisches Glied (19, 119), das am Endabschnitt des Gehäuses angeordnet ist,
wobei das zweite elastische Glied in Richtung auf den Endabschnitt des Katheters verläuft und sich innerhalb des ersten elastischen Glieds befindet;

dadurch gekennzeichnet, daß

- das zweite elastische Glied eine Spule ist.

2. Ultraschall-Bildgebungskatheter nach Anspruch 1, wobei eine Länge eines Abschnitts des zweiten elastischen Glieds, der in das erste elastische Glied eingefügt ist, 0,5 bis 20 mm beträgt.

3. Ultraschall-Bildgebungskatheter nach einem der vorhergehenden Ansprüche, wobei die äußere Umhüllung eine Verstärkungsschicht mit einem spiralförmigen Schlitz aufweist, der an einem Endabschnitt davon vorgesehen ist.


5. Ultraschall-Bildgebungskatheter nach einem der vorhergehenden Ansprüche, wobei das erste elastische Glied ein Durchgangslöch umfaßt, das zwischen dem Inneren und dem Äußeren des Katheters verbindet.

6. Ultraschall-Bildgebungskatheter nach einem der vorhergehenden Ansprüche, wobei sich ein Durchmesser des zweiten elastischen Glieds zum Endabschnitt des Katheters hin verjüngt.

7. Ultraschall-Bildgebungskatheter nach einem der vorhergehenden Ansprüche, wobei sich ein Durchmesser des ersten elastischen Glieds zum Endabschnitt des Katheters hin verjüngt.

8. Ultraschall-Bildgebungskatheter nach einem der vorhergehenden Ansprüche, wobei das erste elastische Glied ein Halteglied aufweist, das in einen Abschnitt des ersten elastischen Glieds eingefügt ist.

9. Ultraschall-Bildgebungskatheter nach Anspruch 1, wobei das erste elastische Glied ein Halteglied aufweist, das in einen Endabschnitt des ersten elastischen Glieds eingefügt ist.

10. Ultraschall-Bildgebungskatheter nach einem der vorhergehenden Ansprüche, wobei der Ultraschallwellenszillator einen Ultraschallwellensollsillationsbereich umfaßt, der in einem Ultraschallwellenwandler beinhaltet ist.

11. Ultraschall-Bildgebungskatheter (50) nach einem der vorhergehenden Ansprüche, wobei das Gehäuse aus einem Isoliermaterial ausgebildet ist.

12. Ultraschall-Bildgebungskatheter nach Anspruch 11, wobei das Gehäuse aus Keramik ausgebildet ist.

13. Ultraschall-Bildgebungskatheter nach Anspruch 12, wobei die Keramik Aluminiumoxid oder Zirkondioxid ist.


15. Ultraschall-Bildgebungskatheter (100), umfassend:

- eine äußere Umhüllungsbaugruppe (102) mit einer äußeren Schicht (102a) und einer inneren Schicht (102c) und einer Endseite und einem Endabschnitt;
- eine Antriebswelle (106), die in der äußeren Umhüllungsbaugruppe angeordnet ist;
- ein Gehäuse (127) das an der Antriebswelle befestigt ist und in dem ein Ultraschallwellenszillator (11) angeordnet ist, wobei das Gehäuse einen Endabschnitt aufweist und das Gehäuse sich innerhalb eines Endabschnitts der äußeren Umhüllungsbaugruppe befindet;
- ein erstes elastisches Glied (141), das am Endabschnitt der äußeren Umhüllungsbaugruppe und an einem Endabschnitt des Katheters und zwischen der äußeren Schicht und der inneren Schicht angeordnet ist;
- ein zweites elastisches Glied (119), das am Endabschnitt des Gehäuses angeordnet ist, wobei das zweite elastische Glied in Richtung auf den Endabschnitt des Katheters verläuft und sich innerhalb des ersten elastischen Glieds befindet;

dadurch gekennzeichnet, daß

- das zweite elastische Glied eine Spule ist.

16. Ultraschall-Bildgebungskatheter nach Anspruch 15, wobei die äußere Umhüllungsbaugruppe ein Endglied aufweist, das mit dem Ende der äußeren Umhüllungsbaugruppe verbunden ist und eine Öffnung aufweist.

17. Ultraschall-Bildgebungskatheter nach Anspruch 15, wobei die äußere Umhüllungsbaugruppe ein geschlossenes Endglied aufweist, das mit dem En-
catedation 1, dans lequel la longueur de la partie du second organe élastique qui est insérée dans le premier organe élastique est comprise entre 0,5 et 20 mm.

3. Cathéter pour imagerie ultrasonore selon l'une des revendications précédentes, dans lequel la gaine externe a une couche d'armature ayant une fente spirale disposee vers une partie de bout de cette couche.

4. Cathéter pour imagerie ultrasonore selon l'une quelconque des revendications précédentes, dans lequel une partie au moins du second organe élastique est formée d'un métal super-élastique.

5. Cathéter pour imagerie ultrasonore selon l'une quelconque des revendications précédentes, dans lequel le premier organe élastique a une fente disposée vers une partie de bout du cathéter.

6. Cathéter pour imagerie ultrasonore selon l'une quelconque des revendications précédentes, dans lequel la longueur de la partie du second organe élastique qui est insérée dans le premier organe élastique est comprise entre 0,5 et 20 mm.

7. Cathéter pour imagerie ultrasonore selon l'une quelconque des revendications précédentes, dans lequel le diamètre du second organe élastique diminue vers la partie de bout du cathéter.

8. Cathéter pour imagerie ultrasonore selon l'une quelconque des revendications précédentes, dans lequel le diamètre du premier organe élastique diminue vers la partie de bout du cathéter.

9. Cathéter pour imagerie ultrasonore selon la revendication 1, dans lequel le premier organe élastique a un organe de support inséré dans une partie de bout du premier organe élastique.

10. Cathéter pour imagerie ultrasonore selon l'une quelconque des revendications précédentes, dans lequel l'oscillateur ultrasonore comprend une section d'oscillation d'ondes ultrasonores incorporée à un transducteur d'ondes ultrasonores.

11. Cathéter pour imagerie ultrasonore selon l'une quelconque des revendications précédentes, dans lequel le boîtier est formé d'un matériau isolant.

12. Cathéter pour imagerie ultrasonore selon la revendication 11, dans lequel le boîtier est formé d'une céramique.

Recommandations

1. Cathéter (1, 30, 40, 50, 100) pour imagerie ultrasonore, comprenant :

   une gaine externe (2, 102) destinée à être insérée dans une cavité corporelle, la gaine externe ayant un côté de bout et une partie de bout,
   une tige d'entraînement (6, 106) disposée dans la gaine externe et destinée à transmettre une force d'entraînement mécanique d'un côté proximal à un côté de bout de la tige d'entraînement, la tige d'entraînement pouvant être entraînée en rotation par une source externe d'entraînement (8, 16),
   un boîtier (27, 127) fixé à la tige d'entraînement et dans lequel sont disposés un oscillateur ultrasonore (3, 11, 111) ou à la fois un oscillateur ultrasonore et un réflecteur d'ondes ultrasonores, le boîtier ayant une partie de bout et le boîtier étant disposé à l'intérieur d'une partie de bout de la gaine externe,
   un premier organe élastique (41, 141) disposé à la partie de bout de la gaine externe et à une partie de bout du cathéter, et
   un second organe élastique (19, 119) disposé à la partie de bout du boîtier, le second organe élastique s'étendant vers la partie de bout du cathéter et étant disposé à l'intérieur du premier organe élastique,

   caractérisé en ce que le second organe élastique est un enroulement.

2. Cathéter pour imagerie ultrasonore selon la reven-
14. Cathéter pour imagerie ultrasonore selon l'une quelconque des revendications 11 à 13, dans lequel le boîtier a une forme cylindrique et comprend une partie coupée destinée à loger l'oscillateur ultrasonore au centre dans une direction axiale du boîtier cylindrique, l'oscillateur étant logé de manière que la partie coupée soit au contact du boîtier.

15. Cathéter (100) pour imagerie ultrasonore, comprenant :

- un ensemble (102) formant une gaine externe ayant une couche externe (102a) et une couche interne (102c), et un côté de bout et une partie de bout,
- une tige d’entraînement (106) disposée dans l’ensemble gaine externe,
- un boîtier (127) fixé à la tige d’entraînement et dans lequel est disposé un oscillateur ultrasonore (11), le boîtier ayant une partie de bout et étant disposé à l’intérieur d’une partie de bout de l’ensemble gaine externe,
- un premier organe élastique (141) disposé à la partie de bout de l’ensemble gaine externe et à la partie de bout du cathéter et entre les couches externe et interne, et
- un second organe élastique (119) disposé à la partie de bout du boîtier, le second organe élastique s’étendant vers la partie de bout du cathéter et étant disposé à l’intérieur du premier organe élastique,

 caractérisé en ce que le second organe élastique est un enroulement.

16. Cathéter pour imagerie ultrasonore selon la revendication 15, dans lequel l’ensemble gaine externe a un organe de bout raccordé au bout de l’ensemble gaine externe et ayant une ouverture.

17. Cathéter pour imagerie ultrasonore selon la revendication 15, dans lequel l’ensemble gaine externe a un organe de bout fermé raccordé au bout de l’ensemble gaine externe et le cathéter a un espace interne fermé rempli d’un liquide.

18. Cathéter pour imagerie ultrasonore selon l’une quelconque des revendications 15 à 17, dans lequel une partie de corps de l’ensemble gaine externe a une couche d’armature entre la couche externe et la couche interne.

19. Cathéter pour imagerie ultrasonore selon la revendication 18, dans lequel la couche d’armature a une fente spiralée disposée vers une partie de bout de celle-ci.

20. Cathéter pour imagerie ultrasonore selon l’une quelconque des revendications 15 à 19, dans lequel l’oscillateur ultrasonore comprend une section d’oscillation d’ondes ultrasonores incorporée à un transducteur d’ondes ultrasonores.